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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR		ATTORNEY DOCKET NO.
09/276,484	03/25/99	GAIGER	A	210121.465C1

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EXAMINER	
SCHWADRON, R	
ART UNIT	**PAPER NUMBER**
1644	13

DATE MAILED: 05/16/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
09/276,484	Gaiger et al.
Examiner	**Art Unit**
Ron Schwadron, Ph.D.	1644

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on 2/20/2001

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-103 is/are pending in the application.

4a) Of the above, claim(s) 1-34, 38, 56, 58-62, 70-107 is/are withdrawn from consideratio

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 35-37, 39-55, 57, 63-69 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claims _____ are subject to restriction and/or election requirement

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13)☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a)☐ All b)☐ Some* c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15)☒ Notice of References Cited (PTO-892)

16)☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)

17)☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____

18)☐ Interview Summary (PTO-413) Paper No(s). _____

19)☐ Notice of Informal Patent Application (PTO-152)

20)☐ Other:

1. Applicant's election of Group VII and the species SEQ. ID. 144 in Paper No. 12 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse. See MPEP § 818.03(a))

2. Claims 1-34,38,59-62,70-103, 56, 58 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected inventions or species, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 12.

3. Claims 35-37,39-55,57,63-69 are under consideration. The claims are under consideration only to the extent that the read on the elected invention (eg. a method of treatment using peptides).

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any
> person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 35-37,39-55,57,63-69 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The specification does not provide adequate written description of the claimed invention. The legal standard for sufficiency of a patent's (or a specification's) written description is whether that description "reasonably conveys to the artisan that the inventor had possession at that time of the. . .claimed subject matter", Vas-Cath, Inc. V. Mahurkar, 19 U.S.P.Q.2d 1111 (Fed. Cir. 1991). In the instant case, the specification does not convey to the artisan that the applicant had possession at the time of invention of the claimed peptides.

The instant claims recite a variant peptide wherein said peptide encodes an

immunogenic WT1 peptide wherein said peptide binds MHC of an animal (eg. T cell binding requires MHC binding of the peptide). The claims encompass a variant peptide wherein said peptide encodes an immunogenic peptide wherein said peptide binds antisera against WT1. There are thousands of different mammals that express structurally differing MHC molecules that bind different, largely nonoverlapping sets of peptides and the specification provides written description of peptides only derived from mouse or human. In addition, regarding claims that encompass immunogenic peptides which bind human MHC, the art recognizes that there are hundreds of different allotypes of MHC molecules found in humans, wherein each allotype binds a unique set of peptides not bound by a different allotype. Similarly, the specification provides written description of particular peptides that bind WT1 antisera. The claims encompass immunogenic WT1 peptides per se, wherein the specification provides specific examples of a limited set of actual immunogenic WT1 peptides. Thus, the written description provided in the specification is not commensurate with the scope of the claimed inventions. In view of the aforementioned problems regarding description of the claimed invention, the specification does not provide an adequate written description of the invention claimed herein. See The Regents of the University of California v. Eli Lilly and Company, 43 USPQ2d 1398, 1404-7 (Fed. Cir. 1997). In University of California v. Eli Lilly and Co., 39 U.S.P.Q.2d 1225 (Fed. Cir. 1995) the inventors claimed a genus of DNA species encoding insulin in different vertebrates or mammals, but had only described a single species of cDNA which encoded rat insulin. The court held that only the nucleic acids species described in the specification (i.e. nucleic acids encoding rat insulin) met the description requirement and that the inventors were not entitled to a claim encompassing a genus of nucleic acids encoding insulin from other vertebrates, mammals or humans, id. at 1240. In the instant case, the specification has disclosed specific immunogenic peptides which bind MHC or WT1 antisera, while claiming peptides which bind any MHC or antisera against WT1 from any mammal. The Federal Circuit has held that if an inventor is "unable to envision the detailed constitution of a gene so as to distinguish it from other materials. . .conception has not been achieved until reduction to practice has occurred", Amgen, Inc. v. Chugai Pharmaceutical Co, Ltd., 18 U.S.P.Q.2d 1016 (Fed. Cir. 1991). Attention is also directed to the decision of The Regents of the University of California v. Eli Lilly and Company (CAFC, July 1997) wherein is stated: The description requirement of the patent statute

requires a description of an invention, not an indication of a result that one might achieve if one made that invention. See In re Wilder, 736 F.2d 1516, 222 USPQ 369, 372-373 (Fed. Cir. 1984) (affirming rejection because the specification does "little more than outlin[e] goals appellants hope the claimed invention achieves and the problems the invention will hopefully ameliorate."). Accordingly, naming a type of material generally known to exist, in the absence of knowledge as to what that material consists of, is not a description of that material.

Thus, as we have previously held, a cDNA is not defined or described by the mere name "cDNA," even if accompanied by the name of the protein that it encodes, but requires a kind of specificity usually achieved by means of the recitation of the sequence of nucleotides that make up the cDNA. See Fiers, 984 F.2d at 1171, 25 USPQ2d at 1606.

6. Claims 65 and 66 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 65 and 66 lack antecedent basis in claim 63 in the recitation of "wherein the bone marrow, peripheral blood or fraction is obtained".

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

8. Claims 35-37,39-42,45,49,53,55,57,63-65,68,69 are rejected under 35 U.S.C. 102(a) or 102(e) as being anticipated by Chada et al. (US Patent 5,693,522) as

evidenced by Berzofsky et al.

Chada et al. teach a method of cancer immunotherapy wherein immunogenic WT1 peptides which stimulate T cell responses are administered to a patient (see column 1, second paragraph, column 2, column 4, second paragraph, and last paragraph, continued on column 5, column 8, column 14, last two paragraphs and column 15). Chada et al. teach that said WT1 peptide is administered with a pharmaceutically acceptable carrier (see column 15, second paragraph). Chada et al. teach that said WT1 peptide is administered with a non-specific immune enhancer (see column 15, third paragraph). Regarding claim 36, Chada et al. teach use of peptides which induce T cell mediated responses (see column 14, last paragraph, continued on page 15 and column 15, first paragraph) wherein the art recognizes that such peptides can have less than 16 amino acids (eg. see Berzofsky et al., page see page 42, lines 18-21). Killing of tumor cells inhibits the development of disease in treated patients. Chada et al. teach that the aforementioned peptide can be used to treat the WT1 positive Wilms' tumor (see column 8, penultimate paragraph). The peptide taught by Chada et al. comprises SEQ. ID. no. 144 (eg. it encompasses use of use of intact WT1, see column 14, last paragraph). T cells are inherently present in the bone marrow and peripheral blood.

9. Claims 35-37,39-42,45,49,53,55,57,63-65,68,69 are rejected under 35 U.S.C. 102(b) as being anticipated by Berzofsky et al. (WO 94/21287)

Berzofsky et al. teach a method of cancer immunotherapy wherein immunogenic WT1 peptides which stimulate T cell responses are administered to a patient (page 4, first paragraph and claims 1, 5,11,16). Berzofsky et al. teach that said WT1 peptide is administered with a pharmaceutically acceptable carrier (see page 7, lines 1-2.). Berzofsky et al. teach that said WT1 peptide is administered with a non-specific immune enhancer (a dendritic cell). Regarding claim 36, Berzofsky et al. teach use of peptides which induce T cell mediated responses wherein the peptide can be the minimal peptide that can bind MHC (see page 14, first incomplete paragraph) wherein said minimal size is around 10 amino acids (see page 42, lines 18-21). Killing of tumor cells inhibits the development of disease in treated patients. Berzofsky et al. teach that the aforementioned peptide can be used to treat the WT1 positive Wilms' tumor (see pages 14-16). The peptide taught by Berzofsky et al. comprises SEQ. ID. no. 144 (eg. it encompasses use of use of intact WT1,

see column 14, last paragraph). T cells are inherently present in the bone marrow and peripheral blood.

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

11. Claims 35-37,39-42,45,46,49,50,52-54,55,57,63-69 are rejected under 35 U.S.C. 103(a) as obvious over Chada et al. (US Patent 5,693,522) or Berzofsky et al. in view of Silberstein et al.

Chada et al. teach a method of cancer immunotherapy wherein immunogenic WT1 peptides which stimulate T cell responses are administered to a patient (see column 1, second paragraph, column 2, column 4, second paragraph, and last paragraph, continued on column 5, column 8, column 14, last two paragraphs and column 15). Chada et al. teach that said WT1 peptide is administered with a pharmaceutically acceptable carrier (see column 15, second paragraph). Chada et al. teach that said WT1 peptide is administered with a non-specific immune enhancer (see column 15, third paragraph). Regarding claim 36, Chada et al. teach use of peptides which induce T cell mediated responses (see column 14, last paragraph, continued on page 15 and column 15, first paragraph) wherein the art recognizes that such peptides can have less than 16 amino acids (eg. see Berzofsky et al.). Killing of tumor cells inhibits the development of disease in treated patients. Chada et al. teach that the aforementioned peptide can be used to treat the WT1 positive Wilms' tumor (see column 8, penultimate paragraph). The peptide taught by Chada et al. comprises SEQ. ID. no. 144 (eg. it encompasses use of use of intact WT1, see column 14, last paragraph). T cells are present in the bone marrow and peripheral blood. Berzofsky et al. teach a method of cancer immunotherapy wherein immunogenic WT1 peptides which stimulate T cell responses are administered to a patient (page 4, first paragraph and claims 1, 5,11,16). Berzofsky et al. teach that said WT1 peptide administered with a pharmaceutically acceptable carrier (see page 7, lines 1-2.). Berzofsky et al. teach that said WT1 peptide administered with a non-specific

immune enhancer (a dendritic cell). Regarding claim 36, Berzofsky et al. teach use of peptides which induce T cell mediated responses wherein the peptide can be the minimal peptide that can bind MHC (see page 14, first incomplete paragraph) wherein said minimal size is around 10 amino acids (seepage 42, lines 18-21). Killing of tumor cells inhibits the development of disease in treated patients. Berzofsky et al. teach that the aforementioned peptide can be used to treat the WT1 positive Wilms' tumor (see pages 14-16). The peptide taught by Berzofsky et al. comprises SEQ. ID. no. 144 (eg. it encompasses use of use of intact WT1, see column 14, last paragraph). T cells are present in the bone marrow and peripheral blood. Neither reference teaches treatment of breast cancer. Neither reference teaches the method of claims 66,67. Silberstein et al. teach that high levels of WT1 are expressed in certain types of breast cancers (see abstract). It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have created the claimed invention because Chada et al. or Berzofsky et al. teach a method of cancer immunotherapy wherein immunogenic WT1 peptides which stimulate T cell responses are administered to a patient having a tumor which expresses WT1, while Silberstein et al. teach that high levels of WT1 are expressed in certain types of breast cancers. Regarding
the methods of claims 66,67, Chada et al. or Berzofsky et al. teach that T cells can be stimulated by WT1 peptides and said steps recite art known steps found in in vitro methods for T cell cloning. One of ordinary skill in the art would have been motivated to do the aforementioned to determine tumor specific epitopes in breast cancer patients.

12. Claims 35-37,39-45,47-49,51-53,55,57,63-69 are rejected under 35 U.S.C. 103(a) as obvious over Chada et al. (US Patent 5,693,522) or Berzofsky et al. in view of Inoue et al.

Chada et al. teach a method of cancer immunotherapy wherein immunogenic WT1 peptides which stimulate T cell responses are administered to a patient (see column 1, second paragraph, column 2, column 4, second paragraph, and last paragraph, continued on column 5, column 8, column 14, last two paragraphs and column 15). Chada et al. teach that said WT1 peptide administered with a pharmaceutically acceptable carrier (see column 15, second paragraph). Chada et al. teach that said WT1 peptide administered with a non-specific immune enhancer (see column 15, third paragraph). Regarding claim

36, Chada et al. teach use of peptides which induce T cell mediated responses (see column 14, last paragraph, continued on page 15 and column 15, first paragraph) wherein the art recognizes that such peptides can have less than 16 amino acids (eg. see Berzofsky et al.). Killing of tumor cells inhibits the development of disease in treated patients. Chada et al. teach that the aforementioned peptide can be used to treat the WT1 positive Wilms' tumor (see column 8, penultimate paragraph). The peptide taught by Chada et al. comprises SEQ. ID. no. 144 (eg. it encompasses use of use of intact WT1, see column 14, last paragraph). T cells are present in the bone marrow and peripheral blood. Berzofsky et al. teach a method of cancer immunotherapy wherein immunogenic WT1 peptides which stimulate T cell responses are administered to a patient (page 4, first paragraph and claims 1, 5,11,16). Berzofsky et al. teach that said WT1 peptide administered with a pharmaceutically acceptable carrier (see page 7, lines 1-2.). Berzofsky et al. teach that said WT1 peptide administered with a non-specific immune enhancer (a dendritic cell). Regarding claim 36, Berzofsky et al. teach use of peptides which induce T cell mediated responses wherein the peptide can be the minimal peptide that can bind MHC (see page 14, first incomplete paragraph) wherein said minimal size is around 10 amino acids (seepage 42, lines 18-21). Killing of tumor cells inhibits the development of disease in treated patients. Berzofsky et al. teach that the aforementioned peptide can be used to treat the WT1 positive Wilms' tumor (see pages 14-16). The peptide taught by Berzofsky et al. comprises SEQ. ID. no. 144 (eg. it encompasses use of use of intact WT1, see column 14, last paragraph). T cells are present in the bone marrow and peripheral blood. Neither reference teaches treatment of breast cancer. Neither reference teaches the method of claims 66,67. Inoue et al. teach that high levels of WT1 are expressed in certain types of leukemia including ALL (see abstract). It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have created the claimed invention because Chada et al. or Berzofsky et al. teach a method of cancer immunotherapy wherein immunogenic WT1 peptides which stimulate T cell responses are administered to a patient having a tumor which expresses WT1, while Inoue et al. teach that high levels of WT1 are expressed in certain types of leukemias. Regarding the methods of claims 66,67, Chada et al. or Berzofsky et al. teach that T cells can be stimulated by WT1 peptides and said steps recite art known steps found in in vitro methods for T cell cloning. One of ordinary skill in the art would have been motivated to

do the aforementioned to determine tumor specific epitopes in leukemia patients.

13. No claim is allowed.

14. Papers related to this application may be submitted to Group 1600 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). Papers should be faxed to Group 1600 at (703) 308-4242.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Ron Schwadron whose telephone number is (703) 308-4680. The examiner can normally be reached Monday through Thursday from 7:30 to 6:00. A message may be left on the examiners voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ms. Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 receptionist whose telephone number is (703) 308-0196.

Ron Schwadron, Ph.D.
Primary Examiner
Art Unit 1644
May 2, 2001

RONALD B. SCHWADRON
PRIMARY EXAMINER
GROUP ~~1800~~ 1600